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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,679	05/22/2001	Jennifer L. Hillman	PF-0629 USN	3074

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,679

Applicant(s)

HILLMAN ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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DETAILED ACTION

Status of the Application

[1] Claims 1-20 are pending in the application.

[2] The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Sequence Compliance

[3] It is noted that non-ASCII "garbage" has been deleted from the sequence listing in order for the sequence listing to be compliant and entered into the database. Specifically, the deleted non-ASCII "garbage" is "PF-0629 PCT" and "3/" at the end of the sequence listing for SEQ ID NO:58. Also, an obvious error was corrected by placing reference to each provisional application and its corresponding filing date each on a separate line. Information regarding these corrections can be obtained by contacting (703) 308-4266.

Lack of Unity

[4] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

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Groups I-XXIX, claims 1, 2, 14, 15, and 19, drawn to the special technical feature of a purified polypeptide, the first claimed method of making a polypeptide, a pharmaceutical composition comprising a polypeptide, and the first claimed method of use, i.e., a method for treating or preventing a disorder. Group I recites SEQ ID NO:1, Group II recites SEQ ID NO:2, Group III recites SEQ ID NO:3,... ..and Group XXIX recites SEQ ID NO:29.

Groups XXX-LVIII, claims 3-13, drawn to the special technical feature of an isolated and purified polynucleotide, the first claimed method of use, i.e., a method for detecting a polynucleotide, an expression vector, and a host cell. Group XXX recites a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:30, Group XXXI recites a nucleic acid encoding SEQ ID NO:2 including SEQ ID NO:31, Group XXXII recites a nucleic acid encoding SEQ ID NO:3 including SEQ ID NO:32,... ..and Group LVIII recites a nucleic acid encoding SEQ ID NO:29 including SEQ ID NO:58.

Groups LIX-LXXXVII, claim 16, drawn to the special technical feature of a purified antibody that binds to a polypeptide. Group LIX recites an antibody that binds SEQ ID NO:1, Group LX recites an antibody that binds SEQ ID NO:2, Group LXI recites an antibody that binds SEQ ID NO:3,... ..and Group LXXXVII recites an antibody that binds SEQ ID NO:29.

Groups LXXXVIII-CXVI, claim 17, drawn to the special technical feature of a purified agonist of a polypeptide. Group LXXXVIII recites an agonist of SEQ ID NO:1, Group LXXXIX recites an agonist of SEQ ID NO:2, Group XC recites an agonist of SEQ ID NO:3,... ..and Group CXVI recites an agonist of SEQ ID NO:29.

Groups CXVII-CXLV, claims 18 and 20, drawn to the special technical feature of a purified antagonist of a polypeptide and the first claimed method of use, i.e., a method for treating or preventing a disorder. Group CXVII recites an antagonist of SEQ ID NO:1, Group CXVIII recites an antagonist of SEQ ID NO:2, Group CXIX recites an antagonist of SEQ ID NO:3,... ..and Group CXLV recites an antagonist of SEQ ID NO:29.

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[5] The inventions listed as Groups I-CXLV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

[6] According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. The polypeptides of Groups I-XXIX lack common structure, the polynucleotides of Groups XXX-LVIII lack common structure, the antibodies of Groups LIX-LXXXVII lack common structure, the agonists of Groups LXXXVIII-CXVI lack common structure, and the antagonists of Groups CXVII-CXLV lack common structure and thus, the compounds are not regarded as being of similar nature because all the alternatives do not share a common structure.

[7] According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-CXLV do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-XXIX is a purified polypeptide and the technical feature of Groups XXX-LVIII is an isolated and purified polynucleotide. The polypeptides of Groups I-XXIX and the polynucleotides of Groups XXX-LVIII are shown to lack novelty or inventive step because these technical features are not contributions over the prior art as claims drawn to polypeptides comprising fragments of the polypeptides (e.g., claim 1) and the respective encoding nucleic acids (e.g., claim 9) read on *any* purified polypeptide or *any* isolated encoding nucleic acid. Thus, Groups I-CXLV share no special technical feature.

[8] Pursuant to 37 C.F.R. § 1.475 (d), where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention comprises the first-recited product, methods of making and use thereof. Further pursuant to 37 C.F.R. § 1.475 (d), any feature which the subsequently recited methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such methods

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accordingly defines a separate invention. The claims drawn to the main invention are as follows: claims 1, 2, 14, 15, and 19 reciting SEQ ID NO:1.

[9] It is noted that claims 1-20 will be examined only to the extent the claims read on the elected subject matter.

[10] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[11] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

RS 06/30/03